REMARKS

Applicants respectfully request reconsideration. Claim 19 was previously pending in this application. No claims are amended, added or cancelled. As a result, claim 19 is still pending and is an independent claim. No new matter has been added.

Rejection Under 35 U.S.C. 112

Claim 19 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. According to the Office Action the "specification does not provide sufficient description of the claimed invention by actual reduction to practice." The Office Action further states that the "instant specification fails to evidence that Applicants are in possession of the claimed invention by actual reduction to practice." (Office Action page 4 1st paragraph).

An actual reduction to practice and working examples are not required to demonstrate that Applicants had possession of the invention. According to MPEP 2163.02 "An objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.'....to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed." In the instant application, Applicants provided a written description of the invention that demonstrated Applicants were in possession of the claimed invention. In the specification it is taught that oligonucleotides containing an unmethylated CpG are useful in conjunction with an allergen for treating allergy (page 8 lines 14-16 and page 41 lines 15-29). Thus, Applicants described the invention in the application in a manner sufficient to demonstrate possession of the invention.

The Office Action page 4 through page 7 includes sections taken from the MPEP stating the various teachings related to the written description requirement. The teachings of the MPEP are not applied to the pending claims. It is unclear what the relevance of the specific sections are, short of summarizing various aspects of the written description requirement.

For instance, the Office Action teaches on page 4 that the claimed invention may not be adequately described where an invention is described in terms of a method of its making coupled with its function and there is no described correlation between structure and function. The statement implies that the claims do not set forth any function or specific structure for the claimed oligonucleotides. Contrary to Examiner's assertions, the claimed invention is not described solely in terms of methods of its making coupled with its function. There is correlation between the structure of the invention and its function. As discussed in the specification, the invention is based in part on the finding that immune stimulatory effects of bacterial DNA are a result of the presence of unmethylated CpG dinucleotides in particular base contexts (CpG motifs), which are common in bacterial DNA, but methylated and underrepresented in vertebrate DNA. The immune stimulatory effects of bacterial DNA can be mimicked with synthetic oligodeoxynucleotides containing these CpG motifs. These immune stimulatory effects of CpG ODN are highly CpG specific in that the effects are dramatically reduced if the CpG motif is methylated, changed to a GpC, or otherwise eliminated or altered. The CpG oligonucleotides have several uses including desensitization therapies for the treatment of allergy.

The biomolecule sequences of the invention are not described merely by functional characteristics. The biomolecule sequences of the invention are described by structure, formula, name, and physical properties – as oligonucleotides with specific sequences, specific lengths, and specific internucleotide linkages. In addition, modifications to the bases, nucleosides, and the linkages as envisaged by the instant invention are also described. The specific sequence requirements, linkages and structures of the oligonucleotides of the instant invention are shown the summary of the invention and the detailed description. The specification describes the structures and function of the novel oligonucleotides that comprise the invention.

A skilled artisan can immediately envision the product claimed from the disclosure. A skilled artisan could easily select an appropriate oligonucleotide based on the disclosure that includes the core CpG motif and that would stimulate the desired immunogenic response. Furthermore, a skilled artisan could easily synthesize and use such a compound because the art of nucleic acid synthesis, formulation and administration is well developed and such a process would

not be beyond what is routinely carried out in the art. The specification teaches one of ordinary skill in the art *de novo* synthesis of nucleic acids can be accomplished.

On pages 7-8 it is stated that "nothing exists in the specification to demonstrate that Applicants are in possession of a 5'CpG3' immunostimulatory oligonucleotide for use in a method of treating an allergic response to an antigen or allergy related disorder during antigen specific immunotherapy of a subject.....In the absence of any evidence demonstrating that Applicants are in possession of the active ingredient for the claimed method, the skilled artisan cannot reasonably conclude or recognize that Applicants are in possession of the claimed invention." Applicants disagree.

Applicants have provided examples in the specification showing production of IL-6 in vivo (Example 8) as well as production of IL12 and IFNγ (page 17 first paragraph) as well as other cytokines (Tables 5-7). Additionally Example 12 describes a mouse model of allergic asthma. The combination of these data was adequate to demonstrate to one of skill in the art at the time of the invention that CpG oligonucleotides would be useful in the treatment of allergic disease. Applicants assert that a correlation between CpG oligonucleotides and their use in the treatment and/or prevention of allergy and the description provided in the specification demonstrates that Applicants had possession of the invention at the time the specification was filed. The Examiner has not met her burden for establishing that Applicants teachings in the specification combined with the data fail to demonstrate that Applicants had possession of the claimed invention.

Double Patenting Rejection

Claim 19 has been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-11 and 13-30 of copending Application No. 09/818918. Applicants elect to defer substantive rebuttal of the rejection until such time as the cited application is allowed.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

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